

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION		DISTRICT ADDRESS AND PHONE NUMBER 1401 Rockville Pike HFM-605 Rockville, MD 20852 301-827-6191	
NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: <del>Dr. Robert C. Myers</del> <i>Faud EL-Hibri</i>		PERIOD OF INSPECTION 10/19-23/98	C. F. NUMBER
TITLE OF INDIVIDUAL <del>Chief Operating Officer</del> <i>Chief Executive Officer</i>		TYPE ESTABLISHMENT INSPECTED 924 Blood Derivative & Vaccine Mfg.	
FIRM NAME <del>Bio Port Corporation</del>		NAME OF FIRM, BRANCH OR UNIT INSPECTED Same	
STREET ADDRESS 3500 N. Martin Luther King Jr. Blvd.		STREET ADDRESS OF PREMISES INSPECTED Same	
CITY AND STATE (Zip Code) Lansing, MI 48909		CITY AND STATE (Zip Code) Same	
DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:			
<p>1. Stability testing has not always been performed in accordance with stability protocols, for example:</p> <p style="padding-left: 40px;">Anthrax Vaccine, lot FAV040, was scheduled for 6 month stability testing on 6/2/98. Potency testing at this time point has not yet been performed.</p> <p style="padding-left: 40px;">Anthrax Vaccine, lot FAV013, was scheduled for 6 month stability testing on 6/22/98. Potency testing at this time point has not yet been performed. This lot failed to meet the stability specification for Phemerol on 6/24/98. To date, this result has not been reviewed by the Quality unit. This lot was redated 11/22/94.</p> <p style="padding-left: 40px;">Anthrax Vaccine, lot FAV010, was scheduled for 6 month stability testing on 4/7/98. Potency testing at this time point was not performed. This lot is currently being tested for potency for the 12 month time point. This lot was redated 10/11/94.</p> <p>2. The Quality Review Board has not addressed the failure of Diphtheria Tetanus Toxoid, lot #DT4176, to meet its potency specification for Diphtheria Toxoid at the 3 month stability time point.</p> <p>3. CBER has not been notified in accordance with Error and Accident reporting of the following:</p> <p style="padding-left: 40px;">Rabies Vaccine stability lot #RV152, manufactured on 3/7/96 failed to meet its potency specification on 2/23/98.</p> <p style="padding-left: 40px;">Rabies Vaccine stability lot #RV153, manufactured on 5/6/96 failed to meet its potency specification on 8/28/97 (invalid) and failed to meet potency specifications again on 2/24/98.</p> <p>Investigations into these failures have not included consideration of other lots that may be affected.</p> <p>4. On 6/30/98, the firm installed a new reaction tank mixer on Tank ~~~~~ There is no data documenting that the new mixer is equivalent to the old mixer, including mixing profiles. In addition, CBER has not been notified of this change.</p>			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE <i>Lynette L. Kelley, Robin Lewis</i> <i>James MacLaughlin</i>	EMPLOYEE(S) NAME AND TITLE (Print) Type: Lynette L. Kelley Robin Lewis James MacLaughlin	DATE ISSUED 10/23/98

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NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: <i>Dr. Robert C. Myers</i> <small>Fowl EL-Hibri 928</small>		PERIOD OF INSPECTION 10/19-23/98	C. F. NUMBER
TITLE OF INDIVIDUAL <i>CEO</i>		TYPE ESTABLISHMENT INSPECTED <i>Blood Derivative &amp; Vaccine Mfg.</i>	
FIRM NAME <i>BioPort Corporation</i>		NAME OF FIRM, BRANCH OR UNIT INSPECTED <i>Same</i>	
STREET ADDRESS <i>3500 N. Martin Luther King Jr. Blvd.</i>		STREET ADDRESS OF PREMISES INSPECTED <i>Same</i>	
CITY AND STATE (Zip Code) <i>Lansing, MI 48909</i>		CITY AND STATE (Zip Code) <i>Same</i>	

DURING AN INSPECTION OF YOUR FIRM (WE) OBSERVED:

- Method validation for determination of Phemerol in Anthrax Vaccine excludes accuracy data at the — level for one of two analysts.
- Immune Globulin, lot IG130, did not show preservative effectiveness against several organisms and did not pass Preservative Effectiveness testing according to a report dated 7/13/98.
- There is no established microbial limit for the water in the pasteurizer in Building —, used for heat treatment of Albumin (Human), — vials. In addition, potable water is used for rinsing of the vials of Albumin after heat treatment.
- On 10/20/98, we observed stoppage of the filling line during manufacture of IGIM, lot #IG139, because of mechanical problems with the —. The starwheel was removed, replaced and adjusted, taking approximately 15 minutes. This unexpected maintenance of the capper was not recorded in either the batch record or the Log of Use, Maintenance, and Cleaning (LUMAC). In addition, review of LUMAC logs found that equipment cleaning was not included in these logs.

Repeat Observations:

- The following validations have not been initiated: process validation for the manufacture of Rabies Vaccine; storage of WFI for use in the Rabies manufacturing facility; rabies manufacturing equipment storage time; expiration date for reagents used in the manufacture of Rabies Vaccine.
- SOPs have not been amended to address: when a lot should be monitored on stability when manufacturing deviations occur; time limits for completion of investigations; when senior quality management should be notified of deviations; actions to take when filling is interrupted; additional cleaning and increased sampling when environmental monitoring action limits are exceeded.
- Training of employees performing visual inspection of finished product containers does not include examples of types of particulates and discoloration they are to look for. Finished containers are not held up against a black and white background during inspection. In addition, there is no requirement that employees performing the inspection demonstrate their ability to detect defects.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE <i>Cynthia L. Kelley</i>	EMPLOYEE(S) NAME AND TITLE (Print or Type) Cynthia L. Kelley	DATE ISSUED 10/23/98
	<i>Robin Lewis</i>	Robin Lewis <i>Tubid Inoculation</i>	
	<i>James MacLaughlin</i>	James MacLaughlin	

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NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: <u>Dr. Robert C. Myers</u> Foud EL-Hibi 9/8		PERIOD OF INSPECTION 10/19-23/98	C. F. NUMBER
TITLE OF INDIVIDUAL <u>Chief Operating Officer</u> CEO 9/8		TYPE ESTABLISHMENT INSPECTED <u>Blood Derivative &amp; Vaccine Mfg.</u>	
FIRM NAME <u>Bio Port Corporation</u>		NAME OF FIRM, BRANCH OR UNIT INSPECTED <u>Same</u>	
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DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

12. Qualification of \_\_\_\_\_ cells has not been submitted to CBER.

13. The \_\_\_\_\_ micron filters used to filter compressed air for positive pressure transfer of product in Rabies Vaccine production are not integrity tested.

9/8 10/23/98

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE <u>[Signature]</u> Cynthia L. Kelley, Robin Lewis, James MacLanahan	EMPLOYEE(S) NAME AND TITLE (Print or Type) MAJOR SUPERVISOR Cynthia L. Kelley, Robin Lewis, Jullia L. Gorman, James MacLanahan	DATE ISSUED 10/23/98
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FORM FDA 483 (5/85)

PREVIOUS EDITION MAY BE USED.

INSPECTIONAL OBSERVATIONS PAGE 3 OF 3 PAGES